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Over the past few years there has been increasing confusion as to the necessary qualifications for the use of lasers, the implantation of injectable fillers, and the supervision of ARNPs and PAs. While this article cannot answer all of the questions, it is designed to provide physicians a groundwork from which they may make informed decisions as to how to govern their own practices.

**The Use of Lasers by Non-Physicians**

The use of lasers by non-physicians has been a gray area for cosmetic medicine for several years, yet there does exist some explicit guidance in the Florida Statutes and Florida Administrative Code

Florida Statute 501.122(1) defines a "laser" as "light amplification by stimulated emission of radiation, encompassing wavelengths above and below those in visual range, if produced by laser devices. In turn, "laser device" is defined as "any device designed or used to amplify electromagnetic radiation by stimulated emission."

Subsection (3) of that same statute reads:

- (a) No person licensed to practice the healing arts, nor any other person, may use a Class III or a Class IV laser device or product as defined by federal regulations unless she or she has complied with the rules governing the registration of such devices with the department promulgated pursuant to subsection (2).
- (b) Any person who violates the provisions of this subsection is guilty of a misdemeanor of the second degree, punishable as provided in S. 775.082 or s. 775.083.

However, DOH rules exempt Class IIIA lasers. Therefore, the lasers that must be registered are Class IIB or Class IV, which are those lasers with a wavelength range of at least 710 nanometers with a radiant power of at least  $5 \times 10^{-3}$  power.

### **Laser Hair Removal**

According to F.S. 478.42(5):

*“Electrolysis or electrology” means the permanent removal of hair by destroying the hair-producing cells of the skin and vascular system, using equipment and devices approved by the board (of Medicine) which have been cleared and registered with the United States Food and Drug Administration and that are used pursuant to protocols approved by the board.”*

Therefore, the removal of hair by lasers, IPLs, or any similar device is deemed to be the practice of electrology.

Further, F.S. 478.49(1) states:

*“No person may practice electrology or hold herself or himself out as an electrologist in this state unless the person has been issued a license by the department and holds an active license pursuant to the requirements of this chapter.”*

There are limited exceptions to this rule, as stated in F.S. 478.54, which exempts “a physician licensed under chapter 458, or an osteopathic physician licensed under chapter 459.” The statute does not exempt dentists or chiropractors.

### **Nurses**

Based upon the above, the Board of Nursing has opined in its Declaratory Statement *re Helen M. Serpa, R.N.* that “registered nurses may not perform laser hair removal procedures with a laser device unless the nurse is licensed pursuant to Chapter 478, Florida Statutes.”

### **Cosmetologists**

Many have argued that cosmetologists (a/k/a estheticians) may perform laser or IPL hair removal. In fact, “hair removal” is included in the definition of “cosmetology.” (F.S. 477.013), although FAC 61G5-18.00015 specifically states that “A cosmetologist may also perform non-invasive hair removals, including wax treatments but not including electrolysis as that term is defined in Chapter 478.F.S...”

## **Direct Supervision**

Pursuant to 64B8-56,002 (and Florida Statute 458.348) a specially trained electrologist may perform laser hair removal if he or she works under the direct supervision of a physician licensed under chapter 458 or 459. After much debate and litigation, the Board acquiesced to our definition of direct supervision, to wit:

### **64B8-2.001 Definitions.**

#### *(1) Levels of Supervision:*

*(a) "Direct supervision" shall require the physical presence of the supervising licensee on the premises so that the supervising licensee is reasonably available as needed. When this term is used in probationary terms of a Final Order, it requires that the licensee practice medicine only if the approved supervisor is on the premises.*

As a result, laser hair removal must, at all times, be performed under the direct supervision of a physician. Notwithstanding the above, the Board of Medicine has traditionally held that PAs and ARNPs may also perform laser hair removal, although the statutory authority for such an opinion was lacking until 2006. In 2006, HB 699 exempted from the PA/ARNP satellite supervision requirements those facilities in which PAs and ARNPs were providing only laser hair removal, thereby making at least an implicit admission that these two groups of professionals could perform laser hair removal without physician supervision.

## **Exceptions**

A more recent and disconcerting development has been the Board of Medicine's reluctance to prosecute the use of lasers by medical assistants. Because Florida Statute 458.3485 allows a medical assistant to "operate office medical equipment," the Board of Medicine may not have the authority to prosecute a medical assistant to uses such lasers under the direct supervision of a physician. However, a medical assistant has no ability to make independent decisions, meaning that the physician must, at a minimum diagnose and prescribe the laser hair removal.

## **Conclusion**

In light of the above, and with the possible exception of ARNPs and PAs, laser hair removal may only be performed under the direct supervision of a physician.

### **Other Laser Uses**

Unfortunately, neither federal nor state law regulates the use of lasers for other purposes, and the respective Boards have declined to promulgate rules in the absence of statutory authority.

The Board of Medicine considers "the commercial application of a laser or IPL upon human tissue to be the practice of medicine." That means that physicians, PAs, and ARNPs can use the lasers. Unfortunately, the Board is without statutory authority to enforce that position, although it is used as a guideline when charges are brought against a physician for failure to appropriately supervise a non-physician.

The Board of Nursing refuses to opine directly on the use of lasers by RNs, but it has said unequivocally that RNs may NOT use lasers for laser hair removal under any circumstances; however, in the same opinion the Board declined to opinion an RN's use of lasers for other purposes (see [Serpa](#)). FS 464.003 allows nurses to administer "medications and treatments as prescribed or authorized by a duly licensed practitioner..." That means, at a minimum, the physician must evaluate the patient and authorize the treatment, as the nurse may not legally make a diagnosis or prescribe the treatment. Moreover, FS 458.303(2) states that the Medical Practice Act may not be "construed to prohibit any service rendered by a registered nurse or a licensed practical nurse, if such service is rendered under the direct supervision and control of a licensed physician who provides specific direction for any services to be performed and gives final approval to all services performed."

Likewise, the medical assistant statute (F.S. 458.3485) allows the MA to operate office medical equipment under a physician's direct supervision, but does not allow the MA to make independent decisions.

In recent weeks, much discussion has included the use of lasers by chiropractors. The use of lasers by chiropractors would appear to violate FAC 64B2-17.001, which prohibits chiropractors from "using instruments for treatment, the use of which are not taught in the regular course of instruction in a college recognized by the Board of Chiropractic." Likewise, a chiropractor's performance of laser hair removal would appear to violate F.S. 478.49, which requires an electrologist license to perform electrolysis as defined in FS 476.42, with the only exceptions being physicians licensed under FS chapters 458 or 459 (see FS 478.54).

### **Injectable Fillers**

If the laws on lasers were not vague enough, those on injectable fillers are virtually non-existent.

According to Allergan's website, "BOTOX® Cosmetic is administered by physicians and is available only by prescription."

Restylane, Perlane, and other such fillers are deemed Class III Restricted Medical Devices. Therefore, according to 21 CFR 801.109, it may only be sold pursuant to a prescription and remain "in the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device."

The updated Drug Pedigree Law (HB 7049) was signed into law by Governor Crist on June 18, 2008. As of July 1, 2008, "the distribution of a prescription device to the patient or ultimate consumer without a prescription or order from a practitioner licensed by law to use or prescribe the device" shall be a felony (F.S. 499.005(24)). Moreover, the same statute states that the possession of any drug (such as Botox) without a "pedigree paper," which may only be held by a licensed distributor or dispensing physician, also is a potential felony offense.

Although the medical assistant statute mentioned above allows medical assistants to "perform venipunctures and nonintravenous injections," it may be argued that the implantation of a prescription device (e.g., Restylane) is not within such a definition. Although the Board of Medicine has not opined directly on the subject, FAC 64B8-9.007(2)(a) includes in the definition of "surgery" "insertion of natural or artificial implants." In any event, the above law makes clear that a physician prescription is needed for each patient, and any action by a medical assistant must be under the direct supervision of a physician.

The Board of Nursing has only addressed this issue unofficially. On December 7, 2007, the Board of Nursing issued a statement that "the procedure of botox injection(s) and sclerotherapy is outside the scope of prevailing standards of nursing practice for both the licensed practical nurses and registered nurses in the State of Florida."

### **Physician Supervision in Satellite Facilities**

Florida House Bill 699 was signed into law on June 19, 2006. Among the important provisions of this legislation are physician supervision requirements for satellite offices (offices other than a physician's primary office) that utilize nurse practitioners and physician assistants, with special rules for those satellite offices that practice primarily aesthetic skin care services.. Additionally, the number and location of satellite offices that can be supervised will be limited in number.

Section 5: Amends Florida Statute 458.348 to regulate supervisory relationships in medical office settings.

The provision states, *"A supervisory relationship in medical office setting: A physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising physician, must comply with the standards set forth in this subsection, or the purpose of this subsection, a "physician's primary practice location" means the address reflected on the physician's profile published pursuant to F.S. 456.041*

*(a) A physician who is engaged in providing primary health care services may not supervise more than four offices in addition to the physician's primary practice location. For the purpose of this subsection, "primary health care" means health care services that are commonly provided to patients without referral from another practitioner, including obstetrical and gynecological services, and excludes practices providing primarily dermatological and skin care services, which include aesthetic skin care service." (emphasis added)*

**This section limits to four the number of satellite facilities (in addition to a primary care physician's office) a primary care physician may supervise. A further discussion of the rules for those who provide primarily skin care services is provided in subsection (c).**

*(b) A physician who is engaged in providing specialty health care services may not supervise more than two offices in addition to the physician's primary practice location. For the purpose of this subsection, "specialty health care" means health care services that are commonly provided to patients with a referral from another practitioner and excludes practices providing primarily dermatological and skin services, which aesthetic skin care services.*

**As a result, dermatologists and plastic surgeons may supervise up to two satellite offices in which their nurse practitioners and physician assistants work without the physician present.**

*(c) A physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising physician and the services offered at the office are primarily*

*dermatological or skin care services, which include aesthetic skin care services other than plastic surgery, must comply with the standards listed in subparagraphs 1-4, Notwithstanding s-458.347 (4) (e) 8., a physician supervising a physician assistant pursuant to this paragraph may not be required to review and cosign charts or medical records prepared by such physician assistant.*

*1. The physician shall submit to the board (Board of Medicine) the addresses of all offices where he or she is supervising an advanced registered nurse practitioner or physician's assistant which are not the physician's primary practice location.*

***2. The physician must be board-certified or board-eligible in dermatology or plastic surgery as recognized by the board pursuant to s. 458.3312.***

*3. All such offices that are not the physician's primary place of practice must be within 25 miles of the physician's primary place of practice or in the county that is contiguous to the county of the physician's primary place of practice. However, the distance between any of the offices may not exceed 75 miles.*

*4. The physician may supervise only one office other than the physician's primary place of practice except that until July 1, 2011, the physician may supervise up to two medical offices other than the physician's primary place of practice if the addresses of the offices are submitted to the board before July 1, 2006. Effective July 1, 2011, the physician may supervise only one office other than the physician's primary place of practice, regardless of when the addresses of the offices were submitted to the board.*

This requires PAs and ARNPs who work in satellite offices in which primarily skin care services are offered to be supervised by a board certified plastic surgeon or dermatologist. This is a wonderful patient protection section that will ensure that those supervising these services are properly trained to do so. While the legislation bestows special status upon plastic surgeons and dermatologists, our members should remember that supervision does carry with it responsibility, and that while many of these offices will be present opportunities for our members to become medical directors, members should not do so unless they are prepared to offer true supervision.

Moreover, it is instructive to review what the above does NOT do. Subsection (c) does not affect

1. Facilities in which neither PAs nor ARNPs perform “primarily” skin care services. As long as such a satellite performs primary care, which may include some skin care services, it is regulated under subsection (a);
2. Facilities in which the only service being performed by the ARNP or PA is hair removal;

*(d) A physician who supervises an office in addition to the physician's primary practice location must conspicuously post in each of the physician's offices a current schedule of*

*the regular hours when the physician is present in that office and the hours when the office is open while the physician is not present.*

This section affects all satellites, but does NOT require any minimum presence by the physician, only that the patient is notified if and when a physician is likely to be present.

Quite obviously, the laws concerning these subjects are not absolute and are subject to differing interpretations. Therefore, statutory and/or regulatory clarification is warranted to provide clear guidance on these issues. Nevertheless, the above is designed to provide a rudimentary education regarding the issues surrounding the use of these equipment, drugs, and extenders.

Should members have any questions, they are encouraged to contact General Counsel Chris Nuland at [nulandlaw@aol.com](mailto:nulandlaw@aol.com).